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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,579	06/18/2001	Sujay Singh	IMG-00112.P.1-US	2573

7590 11/14/2002

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EXAMINER
WILSON, MICHAEL C

ART UNIT	PAPER NUMBER
1632	6

DATE MAILED: 11/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/884,579	SINGH ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 6 and 11, drawn to a transgenic bird having a knockout of an endogenous immunoglobulin gene, classified in class 800, subclass 19.

II. Claims 2-5, 7-10 drawn to a transgenic bird having a knockout of an endogenous immunoglobulin gene and an insertion of an exogenous immunoglobulin gene, classified in class 800, subclass 19.

III. Claims 12 and 16, drawn to a method of making an antibody using a transgenic bird immunized with an antigen and isolating the antibody from serum or egg of the bird, classified in class 800, subclass 6.

IV. Claims 13, 15, 17, 19 and 22, drawn to an antibody, classified in class 530, subclass 387.1.

V. Claims 14, 18, drawn to a method of making an antibody using a transgenic bird immunized with an antigen and isolating the antibody from B-cells of the bird, classified in class 800, subclass 4.

VI. Claims 20 and 21, drawn to transfecting cells with DNA encoding an antibody, classified in class 435, subclass 325.

The inventions are distinct, each from the other because of the following reasons:

Groups I and II are patentably distinct because the transgenic bird lacking an immunoglobulin gene can be used to study the role of the gene on the immune system

of birds *in vivo* while the transgenic bird lacking an endogenous immunoglobulin gene and expressing an exogenous immunoglobulin gene can be used to make chimeric antibodies. The protocols and reagents for knocking out a gene are materially distinct and separate than those required to insert an exogenous gene. The knockout bird does not require the bird having a knockout and an exogenous gene because the knockout can be performed by itself. The bird having a knockout and an exogenous gene does not require the knockout because both the knockout and insertion can be performed at the same time.

Groups I and III or V are patentably distinct because the transgenic bird lacking an immunoglobulin gene can be used to study the role of the gene on the immune system of birds *in vivo* while the method of making an antibody in Group III is used to make chimeric antibodies. The protocols and reagents required for making a transgenic bird are materially distinct and separate than those required for using a bird to isolate antibodies. The knockout does not require the method of isolating antibodies and the method of isolating the antibodies does not require the knockout.

Groups I and IV are patentably distinct because the knockouts can be used to study the role of the gene on the immune system of birds *in vivo* while the antibody can be used to isolate protein. The protocols and reagents for transgenics and antibodies are materially distinct and separate. The birds do not require the antibodies and the antibodies do not require the birds.

Groups I and VI are patentably distinct because the knockouts can be used to study the role of the gene on the immune system of birds *in vivo* while transfecting cells

with DNA encoding an antibody can be used to isolate antibodies. The protocols and reagents for making transgenics and for transfecting cells are materially distinct and separate. Transgenics do not require the particulars of the method of transfecting cells for patentability and the method of transfecting cells can be used for purposes other than making transgenics, i.e. isolating antibodies *in vitro*.

Inventions II and III or V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method can be performed in a transgenic bird having an exogenous immunoglobulin gene without having a knockout. In addition, the method can be performed two materially distinct and separate ways (Groups III and V).

Groups II and IV are patentably distinct because the knockout having an exogenous immunoglobulin gene can be used to isolate chimeric antibodies while the antibody can be used to humanize chicken antibodies. The protocols and reagents for transgenics and antibodies are materially distinct and separate. The birds do not require the antibodies and the antibodies do not require the birds.

Groups II and VI are patentably distinct because the knockout having an exogenous immunoglobulin gene can be used to isolate chimeric antibodies *in vivo* while transfecting cells with DNA encoding an antibody can be used to isolate antibodies *in vitro*. The protocols and reagents for making transgenics and for

transfecting cells are materially distinct and separate. Transgenics do not require the particulars of the method of transfecting cells for patentability and the method of transfecting cells can be used for purposes other than making transgenics, i.e. isolating antibodies *in vitro*.

Inventions III and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the method can be used to make various chimeric antibodies, each of which has a different structure and function. In addition, the antibodies can be made using a different process (Group V).

Inventions III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not used together and have different modes of operations. The steps required to search Groups III and V are mutually exclusive, each requiring a separate search. Searching both Groups together would be undue.

Groups III or V and VI are patentably distinct because immunizing a bird with an antigen can be used to isolate chimeric antibodies *in vivo* while transfecting cells with DNA encoding an antibody can be used to isolate antibodies *in vitro*. The protocols and reagents for isolating antibodies *in vivo* and *in vitro* are materially distinct and separate. Transgenics do not require the particulars of the method of transfecting cells for

patentability and the method of transfecting cells can be used for purposes other than making transgenics, i.e. isolating antibodies *in vitro*.

Inventions IV and V or VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the method can be used to make various chimeric antibodies, each of which has a different structure and function. In addition, the antibodies can be made using a different process (Group III).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Groups I-VI are mutually exclusive, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson whose telephone number is 703-305-0120. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

MICHAEL C. WILSON
PATENT EXAMINER